California Health Care Foundation

Dear Officer of the Medical Board of California, December 5, 2018

I am a director at the California Health Care Foundation overseeing our $5 million opioid safety initiative, and we work closely with state leaders in public health and health services. I am reaching out regarding the Medical Board of California's Death Certificate Project. While I appreciate the Board's commitment to address the opioid epidemic, I am concerned that the approach is leading to unintended consequences, potentially causing harm to both patients and physicians. I respectfully offer recommendations for your consideration to address these concerns and potentially increase the effectiveness of the Board's project. I believe minor changes would allow the Board to continue in its mission while adapting to the shifting epidemic in California.

The epidemic is changing: deaths in California from prescribed opioids have stabilized, but heroin and fentanyl death rates are climbing[i]. While there is a clear standard of care for people with opioid addiction, there is no clear standard of care nor consensus about how to manage the other population harmed by opioid overprescribing: patients dependent on long-term, high-dose opioids. We do not have enough providers to care for these patients, and I am concerned the Death Certificate Project could exacerbate the shortage of providers.

Without clear guidelines, it is very difficult for doctors to manage patients on high-dose opioids. Both the Medical Board and CDC guidelines are silent on the issue, other than urging caution and monitoring. The CDC guidelines recommend voluntary tapers to lower doses, but they advise against involuntary tapers. While the 800,000 Californians on high-dose opioids and the almost 700,000 Californians[ii] on opioids and benzodiazepines are clearly at risk of harm if they stay on these regimens, they are also at risk if tapered too quickly or tapered off altogether. Emerging data shows that stopping opioids in these patients more than doubles their use of illicit drugs[iii], and the VA found quadruple the rates of suicidal ideation and/or self-harm[iv].

These patients need high-touch management – physicians who will work with them on a safe, individualized course of care. If the patient does not want to taper, or risks medical or psychiatric destabilization with a taper, the best course of treatment may be to continue the regimen. This leads to a real challenge for Medical Board oversight. A physician could be practicing safe medicine by simultaneously prescribing high-dose opioids and benzodiazepines if the patient has been taking these medications for years. However, if a patient on this regimen overdoses and dies, and is evaluated in the Death Certificate project, the regimen is very likely to be judged by an expert as unsafe. This, despite that fact that the prescriber would have been following CDC guidance to avoid involuntary tapers.[v]

The only way to know the true story is through the medical records. On the surface, it may seem harmless to send out 500 letters to identify twenty-three doctors with violations[vi]. However, there is

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growing concern that the letters are causing harm. I have had conversations with several physicians who report they have changed their prescribing practice, to the detriment of patient care, either from receiving a letter, or knowing someone who has. Recent press reports are increasing physicians' knowledge of the project, and many clinicians have mentioned to me their growing fear that their license could be at risk by continuing to care for complex patients on high opioid doses.

Here are examples:

- Six years ago, an attending physician at a teaching program wrote a prescription, continuing the treatment plan when covering for a resident in training -- a common practice since residents are often on hospital rotations. The patient died shortly afterwards. In 2018, the attending received a Medical Board letter. Since she will not know the status of her license for a year or more,[vii] and she is concerned about this happening again, she has stopped writing opioid prescriptions, even if there are no other coverage options for patients whose resident doctor is unavailable.
- A medical director at community clinic told me he received a letter about a patient that died in 2012. The patient had received a methadone prescription as part of a slow taper from a higher dose previously prescribed by a pain specialist. Since then, this physician has become fearful, abruptly tapering several patients to lower opioid doses and telling his direct reports to do the same. Many of his patients have subsequently left his practice. He feels guilty about the patients but feels even more fearful about prescribing in this environment.
- Two doctors working in different addiction clinics report an uptick in patients using heroin after being "kicked off" high dose opioids, without being offered alternative treatments (e.g. Suboxone).

I have requested data from the California Department of Public Health to understand if we can distinguish between healthy trends (California has cut opioid prescribing almost in half since the peak in 2010)[viii] and unhealthy trends, that could show whether involuntary tapering is leading to bad outcomes. Unfortunately, the analysis is complicated, and it may take several months or a year to get these results. In the meantime, given increase in fentanyl deaths, I think we have reason to be concerned.

The MBC Death Certificate project is quite different than it is for other types of investigations. For example, if a cardiologist receives an investigation letter, the doctor could reasonably trust that the reviewer has objective standards to judge good practice. Heart failure, myocardial infarction, and arrhythmias all have large bodies of evidence to guide care. In contrast, doctors receiving letters about overdose deaths have a real concern: in an area where no data guides practice (we do not yet have large population studies showing tapers improve safety and outcomes), and at a time when standards are evolving, how can clinicians be confident their practice will be judged fairly? If a death happens, the fate of the prescriber's license will depend on the independent judgment of one reviewer, with no clear standard of care, no consensus about good management, and ambiguous guidelines. In that case, a reasonable physician could decide it is safer to avoid accepting new patients on opioids, and to taper existing patients quickly, even though emerging data suggests this practice may put patients at risk of harm.

I propose an alternative approach, one that could produce a higher yield of violations, lessen the impact on appropriate prescribers and their patients, and potentially save lives. This approach involves a minor change to the case-finding methodology: start with outlier prescribers, and then match with death data. This approach has been studied in North Carolina: in 2012, 32-77% of the highest-volume prescribers had written a prescription within 30 days of an overdose death[ix]. By starting with a recent year (e.g. 2017), the Medical Board would identify physicians doing harm at present (as opposed to harm in 2012 – before the CDC and MBC guidelines urged more cautious prescribing). Amid this epidemic, the Board focus its resources on physicians who are currently prescribing unsafely, so we can protect patients who may be at risk in 2018.

Attached are four recommendations, which I hope the Board will consider. The Medical Board of California has a duty to protect the public from bad opioid practices – and the Board also has a duty to ensure whatever action is taken does not put the same public at risk.

Best regards,

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**RECOMMENDATIONS:**

1. **Publicly state that the Medical Board of California aligns with the CDC in opposing involuntary taper policies. Work with experts to give clinicians clear guidance** on how to take care of patients on high-dose or unsafe regimens:

   **Clarify ambiguities** in the Board's guidelines: e.g., that risks and benefits should be reviewed with each patient, that patients should be encouraged to taper to safer, lower doses, but that involuntary tapers are not recommended. Tapers should be halted if the patient shows signs of medical or psychiatric instability. Using long-acting partial agonists (e.g., buprenorphine), should be considered for the indication of pain in patients who are at risk of overdose.

   **Provide educational resources** on how to manage chronic pain patients with opioid and/or benzo dependence: strategies to engage patients in tapering programs, how to mitigate risks in patients who refuse to taper, how to manage common tapering pitfalls. Acknowledge that the evidence is unclear, and there is room for variation.

2. **Amend case-finding recommendations to allow higher yield of unsafe prescribers, and lower yield of good clinicians.**

   Start with sample of clinicians in the top 1st percentile (opioid and benzo volume) and analyze overdose deaths within this outlier cohort (consider methodology described in the Ringwalt[1] paper, which showed, among the top 1% of prescribers, 32-77% had written a prescription within 30 days of an overdose death.) These are the physicians at the most risk of doing harm. Consider working with UC Davis (evaluators with years of experience working with CURES data) to identify a methodology with the highest yield of potential violations. Then crosswalk these physicians with the death data, investigating those who have both risky prescribing (by volume, not through examining an individual patient) and overdose deaths.

3. **Limit investigations to deaths after 2017**.

   **Current deaths are more likely to reflect current unsafe prescribing.** Many of the clinicians investigated from 2012 have already changed their prescribing based on updated information and guidelines. Working on recent deaths will detect prescribers who are currently putting patients at risk, which could prevent overdoses before they occur.

4. **Decrease turnaround time from notification to resolution of case. The current 500+-day turnaround time could be relieved by focusing on a smaller number of physicians at a time.** It is extremely stressful for clinicians to have their license at risk for more than 16 months, and stressed clinicians are unlikely to accept new opioid-dependent patients or continue to treat patients on high-risk regimens. Long investigation times could harm patients.

[1] Ringwalt, et al, (2015). The Use of a Prescription Drug Monitoring Program to Develop Algorithms to Identify Providers with Unusual Prescribing Practices for Controlled Substances. The journal of primary prevention. 36. 10.1007/s10935-015-0397-0.

**END NOTES**

[i] From the California Opioid Surveillance Dashboard: https://discovery.cdph.ca.gov/CDIC/ODdash/

[ii] From the California Opioid Surveillance Dashboard, as of first quarter 2018.

[iii] SF Department of Public Health shows patients discontinued off opioids were more than twice as likely to use illicit drugs compared to those maintained; illicit drugs increasingly are contaminated with fentanyl.

[iv] Demidenko, M., et al, Suicidal ideation and suicidal self-directed violence following clinician-initiated prescription opioid discontinuation among long-term opioid users, *Gen Hosp Psychiatry* 2017 Jul; 47:29-35https://www.ncbi.nlm.nih.gov/pubmed/28807135

[v] The author of the CDC guidelines published recommendations to focus on slow, voluntary tapers of the willing, and for patients too unstable (or unwilling) to taper, to continue current doses and mitigate harm (e.g. through co-prescribing naloxone). Dowell, D, Annals of Internal Medicine, Vol 167 (3), 1 August 2017

[vi] Personal conversation with Kim Kirchmeyer about status as of November 2018

[vii] Personal conversation with Kim Kirchmeyer: average time to resolution is 505 days.

[viii] From the California Opioid Surveillance Dashboard: Q12018 shows the annualized quarterly rate of morphine milligram equivalents per resident at 360.30, compared to 760.14, the peak in 2010.

[ix] Ringwalt, et al, (2015). The Use of a Prescription Drug Monitoring Program to Develop Algorithms to Identify Providers with Unusual Prescribing Practices for Controlled Substances. The journal of primary prevention. 36. 10.1007/s10935-015-0397-0.